UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

DAIICHI SANKYO, LIMITED and DAIICHI SANKYO, INC., **Plaintiffs and Counterclaim Defendants,** **v.** **MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES INC., MATRIX LABORATORIES, LTD., and MYLAN, INC.,** **Defendants and Counterclaim Plaintiffs.**	**Civ. Nos. 2:06-3462, 07-3039, and 08-2752** **OPINION**

WILLIAM J. MARTINI, U.S.D.J.:

Plaintiffs Daiichi Sankyo, Limited and Daiichi Sankyo, Inc. (collectively "Daiichi Sankyo") bring this action seeking clarification of a judgment issued by this Court on August 6, 2009, against Defendants Mylan Pharmaceuticals Inc., Mylan Laboratories Inc., Matrix Laboratories, Ltd. and Mylan, Inc. (collectively "Mylan"). This matter comes before the Court on Plaintiffs' motion for clarification of final judgment under Federal Rule of Civil Procedure 60(a). There was no oral argument. Fed. R. Civ. P. 78(b). For the reasons set forth below, Daiichi Sankyo's motion is **DENIED**.

I. BACKGROUND

Daiichi Sankyo is the inventor and producer of olmesartan medoxomil, the active ingredient in the hypertension medications Benicar, Benicar HCT, and Azor. Mylan Defendants are drug manufacturers seeking to market a generic version of olmesartan medoxomil. Daiichi Sankyo brought a suit against Mylan in this Court, claiming infringement of its United States Patent No. 5,616,599 ("the '599 patent"). Mylan conceded infringement, but countered that the '599 patent was invalid due to obviousness.

The Court held a trial on various days from March 31, 2009 to April 20, 2009, after which the Court ruled in favor of Daiichi Sankyo that Mylan had infringed. ECF Nos. 139, 140. At the Court's direction, Daiichi Sankyo filed a proposed judgment on August 4, 2009. ECF No. 141. After carefully considering Mylan's objections, the Court entered a final judgment ("Judgment") on August 6, 2009. ECF No. 143. The United States Court

of Appeals for the Federal Circuit affirmed the judgment on October 20, 2010. ECF No. 149. The Judgment reads, in pertinent part:

> **ORDERED** that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval by the United States Food and Drug Administration of Mylan's Abbreviated New Drug Applications ("ANDA") Nos. 78-276, 78-827, and 90-398 shall be a date which is not earlier than the expiration date of the '599 patent, including all extensions thereof; and it is further
>
> **ORDERED** that, pursuant to 35 U.S.C. § 271(e)(4)(B), Mylan, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, are enjoined, until the expiration date of the '599 patent, including all extensions thereof, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of the products which are subject of ANDA Nos. 78-276, 78-827, and 90-398; . . . .

Id.

Daiichi Sankyo now moves this Court to clarify this judgment pursuant to Federal Rule of Civil Procedure 60(a). Specifically, it "seeks a revised Judgment . . . that expressly sets forth October 26, 2016 as the earliest date that Mylan can market its generic olmesartan medoxomil products." Mot. for Clarification of Final J. of Aug. 6, 2009, Attach. 1 at 1 ("Pls.' Br."), ECF No. 154. Mylan opposes, arguing that Daiichi Sankyo's motion is improper under Rule 60(a) and that it should be free to launch its products on October 25, 2016. *See* Def.'s Br. in Opp'n to Pls.' Fed. R. Civ. P. 60(a) Mot. 1–3 ("Def.'s Opp'n"), ECF No. 157.

Both parties agree that the '599 patent expired on April 25, 2016. *See* Pls.' Reply Br. to Opp'n to Mot. 1 ("Pls.' Reply"), ECF No. 158 ("The '599 patent undisputedly expired on April 25, 2016 . . . ."); Def.'s Opp'n at 1 ("The '599 patent expired on April 25, 2016."). Both parties also acknowledge that the Food and Drug Administration ("FDA") granted Daiichi Sankyo a "pediatric exclusivity" award on October 7, 2009, which extended Daiichi Sankyo's exclusive marketing rights over olmesartan medoxomil for a period of six months from the date of expiration of the '599 patent. *See* Decl. of Josh Calabro in Supp. of Pls.' Mot. ("Pls.' Decl."), Ex. B at 7; Def.'s Opp'n at 1. The fundamental dispute between the parties is whether that six-month period of exclusivity ends on October 25, as Mylan argues, or October 26, as Daiichi Sankyo argues. Daiichi Sankyo submits that this difference is not trivial, as its average daily sales of olmesartan medoxomil exceed $2.2 million. Pls.' Br. at 1. At its core, the critical relief sought by Daiichi Sankyo is clarification over the following language in the Court's Judgment: "shall be a date which is not earlier than the expiration date of the '599 patent." *See* ECF No. 149.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 60(a) provides: "The court may correct a clerical mistake or a mistake arising from oversight or omission whenever one is found in a judgment, order, or other part of the record." Fed. R. Civ. P. 60(a). The court may correct its mistake on its own or, as here, on motion by a party. *Id*. The rule "applies to every type of judicial decision, regardless of the subject that the court ruled upon." *In re FleetBoston Fin. Corp. Sec. Litig.*, No. 02-cv-4561, 2007 WL 4225832, at *4 (D.N.J. Nov. 28, 2007).

Rule 60(a) "is limited to the correction of 'clerical mistakes'; it encompasses only errors 'mechanical in nature, apparent on the record, and not involving an error of substantive judgment.'" *See Pfizer Inc. v. Uprichard*, 422 F.3d 124, 129–30 (3rd Cir. 2005) (quoting *Mack Trucks, Inc. v. Int'l Union, UAW*, 856 F.2d 579, 584 (3rd Cir. 1988)). The Third Circuit has adopted an applicability test established by the Fifth Circuit, which is:

> [T]he relevant test for the applicability of Rule 60(a) is whether the change affects substantive rights of the parties and is therefore beyond the scope of Rule 60(a) or is instead a clerical error, a copying or computational mistake, which is correctable under the Rule. As long as the intentions of the parties are clearly defined and all the court need do is employ the judicial eraser to obliterate a mechanical or mathematical mistake, the modification will be allowed. If, on the other hand, cerebration or research into the law or planetary excursions into facts is required, Rule 60(a) will not be available to salvage [a party's] blunders. Let it be clearly understood that Rule 60(a) is not a perpetual right to apply different legal rules or different factual analyses to a case. It is only mindless and mechanistic mistakes, minor shifting of facts, and no new additional legal perambulations which are reachable through Rule 60(a).

See Pfizer, 422 F.3d at 130 (quoting *In re W. Tex. Mktg.*, 12 F.3d 497, 504–05 (5th Cir. 1994)). Importantly, the Third Circuit recognizes that "'a motion under Rule 60(a) can only be used to make the judgment or record speak the truth and cannot be used to make it say something other than what was originally pronounced.'" *See In re Diet Drugs Prods. Liab. Litig.*, 200 Fed. App'x 95, 103 (3rd Cir. 2006) (quoting 11 Wright, Miller & Kane, *Federal Practice & Procedure* § 2854 at 240–41).

III. DISCUSSION

The threshold question before the Court is whether the change to the Judgment sought by Daiichi Sankyo's Rule 60(a) motion would alter the rights of the parties from what was originally intended by the Court. *See Pfizer*, 422 F.3d at 129–30; *United States v. Stuart*, 392 F.2d 60, 62 (3rd Cir. 1968) ("[I]t seems to us that Rule 60(a) is concerned primarily with mistakes which do not really attack the party's fundamental right to the judgment at the time it was entered.").

A. The Parties' Arguments

Daiichi Sankyo argues that its motion is proper because it merely asks the Court to revise the Judgment, substituting an affirmative date, October 26, 2016, for the phrases "shall be a date which is not earlier than the expiration date of the '599 patent" and "until the expiration date of the '599 patent." *See* Pls.' Br. at 5–6. According to Daiichi Sankyo, this request is statutorily justified by the Federal Food, Drug, and Cosmetic Act ("FDCA"), which provides that a period of pediatric exclusivity "shall be a period of six months after the date the patent expires (including any patent extensions)[.]" *See id*. at 4 (citing 21 U.S.C. § 355a(b)(1)(B)(i)(II)). Daiichi Sankyo cites to three cases in support of its FDCA interpretation, most notably *Takeda Pharm. Co. Ltd. v. Teva Pharm. USA, Inc.*, which concluded that plaintiff was entitled to "'get the benefit of its exclusive rights until the day after the patent and its related period of exclusivity expires.'" *See id*. at 4–5 (quoting No. 06-33-SLR, 2009 WL 3738738, at *3 (D. Del. Nov. 9, 2009)).

Mylan counters by arguing that Daiichi Sankyo's motion is improper because it seeks to fundamentally alter the parties' rights under the Judgment by retroactively extending the Court's injunction by one day. *See* Def.'s Opp'n at 2–3. Mylan claims that pediatric exclusivity is not an extension of a patent term as governed by 35 U.S.C. §§ 154 and 156, but rather "a regulatory privilege authorized under Title 21 ('Food and Drugs')". *See id*. at 4–5. Thus, the injunction expired with the '599 patent on April 25, 2016. Consequently, the pediatric exclusivity period merely restricted Mylan from taking its generic products to market, but did not restrict it from other pre-market activities that were enjoined by the Judgment but did not require FDA approval. *See id*. at 12–15. The motion, therefore, "improperly requests a *substantive change* to the August 2009 final judgment . . . ." *See id*. at 25.

In its reply, Daiichi Sankyo clarified that it was not seeking an extension of the entire injunction enforced by the Judgment, but that it only seeks "prospective relief, namely, an order barring Mylan from launching its generic olmesartan medoxomil products before October 26." *See* Pls.' Reply at 2. Furthermore, Daiichi Sankyo suggests that the Court need not revise the Judgment, but rather could issue a new order similar to the one issued by the *Takeda* court, which would enjoin Mylan from launching its products until October 26. *See id*. at 11–12.

B. Daiichi Sankyo's Rule 60(a) Motion is Improper

The Court agrees with Mylan that Daiichi Sankyo has improperly employed Rule 60(a) in an effort to fundamentally alter the Judgment. The Third Circuit is unequivocal that Rule 60(a) motions are limited to the correction of errors "mechanical in nature, apparent on the record, and not involving an error of substantive judgment." *See Pfizer*, 422 F.3d at 129–30. Daiichi Sankyo asks the Court to do much more than merely correct a clerical mistake that is obvious from the record. Rather, it asks the Court to apply a statute that is not even recognized by the Judgment *that it drafted*. This request far exceeds the scope of Rule 60(a).

First, and foremost, the Third Circuit is clear that if a Rule 60(a) motion requires a court to research the law or consider facts in depth, then relief is not available under the rule. *See Pfizer*, 422 F.3d at 130 ("'If, on the other hand, cerebration or research into law or planetary excursions into facts is required, Rule 60(a) will not be available to salvage [a party's] blunders.'") (quoting *W. Tex. Mktg.*, 12 F.3d at 504–05). As its briefing demonstrates, Daiichi Sankyo's request requires this Court to undertake exactly that: legal research as to the meaning of 21 U.S.C. § 355a(b)(1)(B)(i)(II) and the applicability of that meaning to the Judgment and the pediatric exclusivity period. *See* Pls.' Br. at 4–9; Pls.' Reply 2–9.

Daiichi Sankyo attempts to distinguish the *Pfizer* decision from the instant motion by arguing that Rule 60(a) also permits correction of mistakes arising from oversight or omission, which the *Pfizer* court did not address in its holding. *See* Pls.' Reply at 9. Daiichi Sankyo grossly misreads *Pfizer* and utterly fails to consider the overwhelming totality of Third Circuit and District of New Jersey case law that categorically rejects its argument. The subject of the Rule 60(a) motion in *Pfizer* was, in fact, an omission by the court's final judgment, which failed to include an order granting prejudgment interest in an arbitration award that was previously agreed upon by the parties. *See Pfizer*, 422 F.3d at 127–28. The Third Circuit held that Rule 60(a) was appropriately applied "where a party seeks to alter a judgment to reflect the District Court's grant of pre-judgment interest . . . ." *See id*. at 130 (citing *Glick v. White Motor Co.*, 458 F.2d 1287, 1294 (3rd Cir. 1972) (holding that once entitlement to pre-judgment interest is established, addition of pre-judgment interest is "merely a ministerial act")). The Magistrate Judge, however, "overstepped his authority under Rule 60(a), and changed the substantive rights of the parties, by requiring that [appellant] sign [appellee's] Settlement Agreement as a condition to receiving her arbitration award. *See id*.

The types of oversights or omissions subject to correction by Rule 60(a) are such inadvertent mistakes made by the Court, which clearly contradict the intentions of the Court, as easily identified by other indications in the record. *Compare id*. (finding that alteration of judgment under Rule 60(a) was proper where the change reflected the court's previous grant of pre-judgment interest), *and Glick*, 458 F.2d at 1293–94 (finding that omission of pre-judgment interest from the judgment was a "clerical mistake" and correctable under Rule 60(a)), *and Stuart*, 392 F.2d at 62–63 (finding that documents inadvertently omitted from the record at the time the judgment was entered constituted the type of correctable error under Rule 60(a)), *and Lawn Doctor, Inc. v. Rizzo*, No. 12-cv-1430, 2015 WL 4320887, at *2 (D.N.J. July 14, 2015) (finding that Rule 60(a) properly applied to exclusion of attorney's fees and costs from order where court had previously granted both), *with Diet Drugs*, 200 Fed. App'x at 104 (finding that Rule 60(a) was not properly applied when the court was required to review and interpret a settlement agreement and apply it to the facts), *and Days Inns Worldwide, Inc. v. JPM, Inc.*, No. 13-cv-3017, 2015 WL 5474882, at *4 (D.N.J. Sept. 15, 2015) (finding that Rule 60(a) motion was improper where it sought to correct errors or omissions from party's own papers).

Here, the omission or oversight that Daiichi Sankyo seeks to correct is the seemingly ambiguous language that *it drafted and submitted to this Court* in its proposed order on August 4, 2009.[1] *See* Pls.' Br. at 5–6; ECF Nos. 141, 143. Whether it be an omission or an oversight, the mistake is not one that was inadvertently made by this Court. Rather, Daiichi Sankyo was afforded ample opportunity to craft the language that it desired and, after affording Mylan the opportunity to object, the Court incorporated that same language that Daiichi Sankyo now claims to be an omission or oversight. The mistake, if it can even be considered that, is solely the responsibility of Daiichi Sankyo and not a correctable error under Rule 60(a). *See Days Inn*, 2015 WL 5474882, at *4.

Second, the relief Daiichi Sankyo seeks is properly provided for under Rule 59(e) or 60(b). Rule 59(e) provides for a party to move for an alteration or amendment of a judgment within 28 days of its entry. Fed. R. Civ. P. 59(e). Rule 60(b) provides for relief from a final judgment for a variety of reasons and must be filed no more than a year after the entry of judgment. *See* Fed. R. Civ. P. 60(b), (c). Indeed, one of the cases cited to by Daiichi Sankyo in support of its proposed revision, *Wyeth v. Teva Pharm. USA Inc.*, is a case from this district where Plaintiffs sought a similar revision concerning pediatric exclusivity under Rule 59(e), not under Rule 60(a). *See* No. 04-cv-2355, 2010 WL 3211126, at *1–2 (D.N.J. Aug. 13, 2010). The Court acknowledges that such revisions were granted under Rule 60(a) by the District of Delaware in *Takeda* and *Alcon, Inc. v. Teva Pharm. USA, Inc.*, but the Court is not persuaded that such an application is the law of this district in light of the aforementioned Third Circuit and District of New Jersey case law. *Compare Alcon, Inc. v. Teva Pharm. USA, Inc.*, No. 06-cv-234, 2010 WL 3081327, at *1 (D. Del. Aug. 5, 2010), *and Takeda*, 2009 WL 3738738 at *1–2, *with supra* p. 5.

By its own admission, Daiichi Sankyo seeks a revision of the Judgment or an entirely new order altogether, not a clarification of the current Judgment. *See* Pls.' Br. at 2, 5–6; Pls.' Reply at 11–12. The proposed alteration would substantively alter the parties' positions with respect to the Judgment—*i.e.*, granting another day of market exclusivity to Daiichi Sankyo. Such an alteration is strictly prohibited under Rule 60(a) and Daiichi Sankyo's motion is, therefore, **DENIED**.

[1] The Court notes that the language in question is not at all ambiguous. The phrase "shall be a date which is not earlier than the expiration date of the '599 patent" clearly establishes that the FDA's approval of Mylan's ANDA shall occur no earlier than April 25, 2016, the date that both parties agree is the expiration date of the '599 patent. As has been noted, however, the FDA granted Daiichi Sankyo a six-month pediatric exclusivity extension of its marketing rights, which effectively extended Daiichi Sankyo's protection from generic competition until October 25, 2016. The FDA's grant did not extend the injunction issued by this Court, as the FDA's own guidance makes clear. *See* Decl. of Shannon Bloodworth in Supp. of Defs.' Br. in Opp'n, Ex. 4 at 13 ("Pediatric exclusivity attaching to the end of a patent term is not a patent term extension under 35 U.S.C. § 156. Rather, it extends the period during which the approval of an abbreviated drug application (ANDA) or 505(b)(2) application may not be made effective by FDA."). Daiichi Sankyo now asks the Court to impute the pediatric exclusivity grant to the Judgment, as a *de facto* extension of the Court's injunction, which it clearly is not. The question of whether Daiichi Sankyo's pediatric exclusivity expires on October 25 or 26, 2016, is a question for the FDA to answer. It has never been before the Court in this case and is wholly improper for the Court to consider under a Rule 60(a) motion.

IV. CONCLUSION

For the reasons stated above, Daiichi Sankyo's Rule 60(a) motion for clarification of judgment is **DENIED**. An appropriate order follows.

/s/ William J. Martini
WILLIAM J. MARTINI, U.S.D.J.

Date: October 20, 2016